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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,121	11/06/2000	Brian Mathur	LEX-0083-USA	8244

24231 7590 03/07/2003

LEXICON GENETICS INCORPORATED
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EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/707,121

Applicant(s)

MATHUR ET AL.

Examiner

Yong Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed December 4, 2002 has been entered.

Claims 2-4 are pending.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Applicant's arguments filed December 4, 2002 have been fully considered but they are not persuasive.

Claims 2-4 remain rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Applicants argue that the nucleic acid molecule encoding the "kinase" of SEQ ID NO:2 has utility (Response, page 2 through 3) kinases have an established utility in the art. The examiner disagrees. The rejection was based on the utility of the particular sequence of SEQ ID NO:1 and not the whole genus of novel human kinases or newly identified genomic sequences. Identifying a polynucleotide as encoding a kinase-like protein does not endow the polynucleotide with such a utility. The specification fails to provide objective evidence of any activity for the encoded proteins or to show that these proteins even exist. Applicant only states that the encoded protein sequence shares

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structural similarity with animal kinases, especially serine/threonine protein kinases (page 2, lines 2-5).

Applicants also argue the nucleic acid molecule encoding the polypeptide of SEQ ID NO:2 has asserted utility since the examiner has stated that SEQ ID NO:1 could be identified as a Rab GTPase since SEQ ID NO:1 shares 99.2% identity to a Rab GTPase. The examiner disagrees. The homology to the Rab GTPase gene was cited to demonstrate that mere homology of SEQ ID NO:1 to a known DNA molecule with a known function does not endow SEQ ID NO:1 with the function because SEQ ID NO:1 could also be a DNA molecule encoding a protein with a different function. Applicants now state on page 2, paragraph 3 of the Response that SEQ ID NO:1 is involved in the control of vesicular traffic in eukaryotic cells, a Rab GTPase. However, the specification points out several times that SEQ ID NO:1 encodes a polypeptide with kinase activity. It is confusing whether applicants are claiming SEQ ID NO:1 as a DNA molecule encoding a kinase or a RAB GTPase, which is not mentioned once in the specification.

Applicants also argue that SEQ ID NO:1 has utility because a knockout mouse has been made wherein SEQ ID NO:1 and 2 were disrupted by retroviral insertion-gene trapping. The specification does not contain such experiments. Further, even if such experiments were part of the original disclosure, the death or illness of the knockout mice does not necessarily indicate that the disrupted gene encodes a kinase. The specification fails to provide objective evidence of any activity for the encoded proteins

Since the specification sets forth no specific function for the encoded protein, the claimed polynucleotides encode a protein with no ascribe function. Therefore, there

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is no specific, substantial, or credible utility that is well known, apparent, or implied by the relationship of the instant polynucleotide to the polynucleotide encoding a kinase.

Claim Rejections - 35 USC § 112

Claims 2-4 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants argue that SEQ ID NO:1 has a specific asserted utility or a well established utility as discussed above. The examiner disagrees, as discussed above.

Since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation. In the state of the art, the function of a polynucleotide is unpredictable from its structure and the functionality of a polynucleotide must be known in order to use the polynucleotide. Therefore, the specification does not teach how to use polynucleotides with unknown function.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner



December 6, 2001